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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/351,057	07/12/1999	JACEK SLON-USAKIEVICZ	06942/021001	9179

7590

03/26/2002

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 03/26/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/351,057

Applicant(s)

SLON-USAKIEVICZ ET AL.

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 2,4 and 6-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 10-27 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1614

DETAILED ACTION

1. Claims 1, 3, 10-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPA 606 804 ('804) in view of Bunnett et al.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Please note, it appears that claims 6-8 are drawn to non-elected subject matter. Therefore, said claims are withdrawn from the rejection and are withdrawn from consideration by the Examiner.

Response to Amendment

The following is responsive to Applicant's remarks received Dec. 31, 2001.

No claims are cancelled. No new claims are added. Claims 1-27 are currently pending.

The previous claims rejection under 35 USC 102(b), set forth in paragraphs 2-3 of the office action mailed, July 31, 2001 **is withdrawn** in view of Applicant's response and the remarks contained therein.

However, Applicant's arguments traversing the previous ground of rejection under 35 USC 103(a) set forth in paragraphs 4-6 of the office action mailed July 31, 2001 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed July 31, 2001 with the following additional comment:

It is essentially Applicant's position that EPA '804 and Bunnett et al. combined fail to disclose or even fairly suggest Applicant's claimed compounds. Specifically, Applicant argues

Art Unit: 1614

that EPA '804 discloses a light-emitting moiety linked to a neurotensin analog through a C=O linkage. Nowhere in EPA '804 is it suggested to link a light emitting moiety through the C=O linkage to a gastrin-releasing peptide to produce a product which exhibits substantial biological activity in the presence of a receptor. Structural modification to a peptide can affect a peptide in a different and unpredictable manner and modification of the neurotensin peptide in EPA '804 through the disclosed linkers would not predictably result in the light emitting gastrin-releasing peptides of the claimed invention. Furthermore, Applicant argues that the prior art does not disclose selecting the light emitting compound having the substantial biological activity from a mixture including secondary compounds that have a biological activity less than .25% of the biological activity of the gastrin-releasing peptide. Concerning the Bunnett et al. reference, said reference merely discloses GRP with red fluorophore cyanin 3.18; however, Applicant claims a light-emitting GRP peptide with substantial biological activity that is selected from relatively inactive fluorescent peptides. Bunnett fails to disclose this limitation.

Said arguments have been considered but are not found to be persuasive.

The Examiner maintains that the motivation to combine is found in EPA '804. The Examiner relies on the Bunnett et al. article to establish that fluorescently labeled GRP analogs are already known in the art. Yet, EPA '804 discloses a means of linking a light emitting moiety to a peptide through a C=O linker. Even though the peptide in EPA '804 is neurotensin and not a gastrin-releasing peptide, EPA '804 **raises expectation of success** by disclosing that conjugating the neurotensin peptide to the fluorophore through the carbon=oxygen bond results in a compound

Art Unit: 1614

that **retains** the "pharmacological" or functional properties that are found in the native peptide, thus producing a compound that is a **non-toxic, highly sensitive marker for identifying receptors of interest**. Please see p. 6, lines 52-58 to p. 7, lines 1-9. Thus, one of ordinary skill in the art, based on this teaching by EPA '804, would be motivated to attach a fluorescent group to a gastrin-releasing peptide through a C=O linker with the expectation that such a modification would result in a fluorescently labeled gastrin-releasing peptide having (1) retained biological activity and (2) high sensitivity for identification of receptors of interest. Therefore the Examiner maintains such a modification would result in a fluorescently labeled gastrin-releasing peptide that retains substantial biological activity.

Concerning Applicant's arguments with respect to selecting the light emitting compound having the substantial biological activity from a mixture including secondary compounds that have a biological activity less than .25% of the biological activity of the gastrin-releasing peptide, since structural modification of peptides by fluorescent labeling may result in modified peptides with activity and some peptides without activity, it would have been obvious to one of ordinary skill in the art to determine and select, after labeling has occurred, only the peptides exhibiting biological activity from those which do not.

It is for these reasons that the rejection is maintained.

Allowable Subject Matter

Art Unit: 1614

Claim 5 is objected to as being dependent upon a rejected base claim. The prior art does not disclose or fairly suggest BODIPY™ conjugated to the claimed peptide via C=O.

New Ground(s) of Rejection

Claim Rejections - 35 USC § 112

3. Claim 18 is vague and indefinite due to use of the trademarks Bodipy™, Alexa™, Iaedans™ in said claim. According to MPEP 2173.05(u),

“it is important to recognize that a trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, **the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product.** Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but **would also constitute an improper use of the trademark or trade name.**”

In this case, the use of the trademarks in claim 18 is improper since it continues to be descriptive of the product that is ultimately bound to the gastrin-releasing protein-based peptide. It is respectfully requested that Applicant cancel the trademark from the claim and add the generic terminology or the chemical name of the compound which Applicant considers to be the preferred light-emitting moiety. For example, one of the chemical names of the compound having the trademark BODIPY® is --dipyrrrometheneboron difluoride--. The specification should also be amended to reflect such changes. Appropriate correction is required.

Art Unit: 1614

Conclusion

Claims 1, 3, 10-27 stand rejected.

Claim 5 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM



March 24, 2002



Cybille Delacroix-Muirheid
Patent Examiner Group 1600